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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,547	12/12/2003	Rich Ewers	USGINZ02511	2408
40518 7590 05/07/2009 LEVINE BAGADE HAN LLP 2400 GENG ROAD, SUITE 120 PALO ALTO, CA 94303				
EXAMINER				
WOO, JULLAN W				
ART UNIT		PAPER NUMBER		
3773				
MAIL DATE		DELIVERY MODE		
05/07/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/734,547

**Applicant(s)**

EWERS ET AL.

**Examiner**

Julian W. Woo

**Art Unit**

3773

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/25/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-19, 32-36 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-19 is/are allowed.
- 6) ☒ Claim(s) 32-36 and 38-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 25, 2009 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 32-36 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deem et al. (6,558,400) in view of Matsui et al. (6,352,503), and further in view of Crockard (5,174,276). Deem et al. disclose the invention substantially as claimed. Deem et al. disclose, at least in figures 6A-6E and col. 8, line 56 to col. 10, line 7; a method of performing endoluminal gastric reduction, where the method includes advancing a plication apparatus (e.g., an endoscopic vacuum-type device 280 as seen in figure 15A) within a patient's stomach; approximating and deploying tissue anchors (110) through each of first and second pluralities of tissue folds in respective first and second planes (to form a smaller pouch), where the tissue folds comprise anterior and posterior segments of the patient's stomach, and where the tissue folds are disposed inferior to the gastroesophageal junction. However, Deem et al. do not disclose an overtube disposed in a flexible state; transitioning the overtube to a rigid state in a desired orientation comprising an arc traversing at least about 180 deg., where the plication apparatus is advanced through a first lumen of the overtube and a gastroscope is advanced through a second lumen. Matsui et al. teach, at least in figures 23 and 44-47 and in col. 11, line 50 to col. 12, line 5 and col. 17, lines 23-45; a method of performing endoluminal gastric reduction including advancing an overtube (101) through a patient's esophagus into the patient's stomach while the overtube is disposed in a flexible state; transitioning the overtube to a rigid state (at 111) in a desired orientation comprising an arc traversing at least about 180 deg. within the patient's stomach and approximating and securing first and second pluralities of tissue folds in respective first and second planes (at 187), where the method includes

advancing a plication apparatus (186) through a first lumen in the overtube and a gastroscope (light guide) through a second lumen (at 114) contained in the overtube. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Matsui et al., to apply a plication apparatus, an overtube, and a gastroscope as claimed in the method of Deem et al. Such modifications would ease access of these tools into the stomach and allow visualization of the stomach as tissue is folded and anchored.

However, Deem et al. in view of Matsui et al. do not disclose that the overtube comprises a plurality of nestable elements, where transitioning the overtube to a rigid state includes imposing a clamping load on the plurality of nestable elements. Crockard teaches, at least in figures 1-2C and col. 1, lines 27-54 and col. 3, line 52 to col. 4 line 25; an overtube comprising a plurality of nestable elements (102), where transitioning the overtube to a rigid state includes imposing a clamping load on the plurality of nestable elements. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Crockard, to modify the overtube of Deem et al. in view of Matsui et al., so that it includes the plurality of nestable elements as claimed. Such a modification would allow the plication apparatus to access a surgical site that is difficult to reach and allow the overtube to be made rigid, so that unwanted movement of the overtube is prevented.

4. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deem et al. (6,558,400) in view of Matsui et al. (6,352,503) and Crockard (5,174,276), and further in view of Harrison (5,403,326). Deem et al. in view of Matsui et al. disclose the

invention substantially as claimed, but do not disclose that the desired orientation of the overtube comprises an arc traversing approximately 270 deg. Harrison teaches, at least in figure 8A, an overtube (58) having an orientation comprising an arc traversing approximately 270 deg. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Harrison, to modify the overtube of Deem et al. in view of Matsui et al. and Crockard, so that it can be oriented as claimed. Such an orientation would allow the overtube to access and visualize tissues in difficult-to-reach locations for the formation of tissue folds.

***Allowable Subject Matter***

5. Claims 11-19 are allowed.
6. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses; a method of endoscopically forming, approximating and securing a plurality of tissue folds, where the method includes, inter alia, advancing an anchor delivery device through the patient's esophagus into the patient's stomach; the anchoring device including a needle defining a lumen; forming a first tissue fold; piercing the tissue fold with the needle, and ejecting a first anchor from the needle across the first tissue fold; forming at least one additional tissue fold, forming at least one additional tissue fold, placing at least one additional anchor across the at least one additional tissue fold, and approximating the plurality of tissue folds.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Response to Amendment***

7. Applicant's arguments with respect to the rejection of claims 32-36, and 38-41 and based on the references of Deem and Matsui et al. have been considered but are not persuasive. First, Deem indeed discloses the method substantially as claimed, where an endoscopic vacuum device (280) is used to form folds in tissue, while anchors (110) are used to secure the folds. The claims do not require that the tissue anchors be deployed by an approximating device, such as element 280, as the Applicant contends. Applicant is reminded that it is the language of the claims itself of the claims which must particularly point out and distinctly claim the subject matter which the Applicant regards as his invention, without limitations imported from the specification. Limitations in the specification not included in the claims may not be relied upon to impart patentability to an otherwise unpatentable claim. In re Lundberg, 113 USPQ 530 (CCPA 1957).

Second, Matsui indeed teaches an overtube transitioned to a rigid state, where the term "rigid state" has been given its broadest reasonable interpretation. That is, Matsui teaches the orientation of an overtube at a momentarily set or firm condition.

Finally, new grounds of rejection of claims 32-36, and 38-41 are presented in view of the amendment.

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773

May 6, 2009